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# TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

Total Number of Pages in This Submission

15 pages +  
1 reference

Application Number

10/025,514

Filing Date

December 18, 2001

First Named Inventor

Philip J. BARR

Group Art Unit

1652

Examiner Name

M. Walicka

Attorney Docket Number

368292000200

## ENCLOSURES (check all that apply)

☒ Fee Transmittal Form + duplicate  
copy for fee processing (2 pages)

☐ Fee Attached

☐ Amendment/Reply

☐ After Final

☐ Affidavits/declaration(s)

☐ Extension of Time Request

☐ Express Abandonment Request

☒ Information Disclosure Statement  
(Supplemental) (3 pages)

☐ Certified Copy of Priority  
Document(s)

☐ Response to Missing Parts/  
Incomplete Application

☐ Response to Missing Parts  
under 37 CFR 1.52 or 1.53

☐ Assignment Papers  
(for an Application)

☐ Drawing(s)

☐ Licensing-related Papers

☐ Petition

☐ Petition to Convert to a Provisional  
Application

☐ Power of Attorney, Revocation  
Change of Correspondence Address

☐ Terminal Disclaimer

☐ Request for Refund

☐ CD, Number of CD(s) \_\_\_\_\_

☐ After Allowance Communication  
to Group

☐ Appeal Communication to Board of  
Appeals and Interferences

☐ Appeal Communication to Group  
(Appeal Notice, Brief, Reply Brief)

☐ Proprietary Information

☐ Status Letter

☒ Other Enclosure(s)  
(please identify below)

- Copy of International Search  
Report dated June 27, 2003  
(7 pages)
- Form PTO-1449 + duplicate  
copy (2 pages)
- One (1) reference
- Return Receipt Postcard

Remarks

## SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm  
or  
Individual Name

MORRISON & FOERSTER LLP  
Eric H. Witt - 44,408

25226

Signature

Date

August 7, 2003

I hereby certify that this correspondence is being deposited with the U.S. Postal Service with sufficient postage as First Class Mail, in an envelope addressed to: Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the date shown below.

Dated: 8/7/03

Signature: Julie M. Hassell

(Julie M. Hassell)



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<b>FEE TRANSMITTAL</b> <b>for FY 2003</b> <small>Patent fees are subject to annual revision.</small>		<b>Compleat if Known</b>																																																																																																																																																																																															
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<input type="checkbox"/> Check <input type="checkbox"/> Credit Card <input type="checkbox"/> Money Order <input type="checkbox"/> Other <input type="checkbox"/> None <input checked="" type="checkbox"/> Deposit Account Deposit Account Number: 03-1952 Deposit Account Name: Morrison & Foerster LLP The Commissioner is hereby authorized to: (check all that apply) <input checked="" type="checkbox"/> Charge fee(s) indicated below <input checked="" type="checkbox"/> Credit any overpayments <input checked="" type="checkbox"/> Charge any additional fee(s) during the pendency of this application <input type="checkbox"/> Charge fee(s) indicated below, except for the filing fee to the above-identified deposit account.		<b>3. 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unavoidable</td><td></td></tr><tr><td>1453</td><td>1,300</td><td>2453</td><td>650</td><td>Petition to revive - unintentional</td><td></td></tr><tr><td>1501</td><td>1,300</td><td>2501</td><td>650</td><td>Utility issue fee (or reissue)</td><td></td></tr><tr><td>1502</td><td>470</td><td>2502</td><td>235</td><td>Design issue fee</td><td></td></tr><tr><td>1503</td><td>630</td><td>2503</td><td>315</td><td>Plant issue fee</td><td></td></tr><tr><td>1460</td><td>130</td><td>1460</td><td>130</td><td>Petitions to the Commissioner</td><td></td></tr><tr><td>1807</td><td>50</td><td>1807</td><td>50</td><td>Processing fee under 37 CFR 1.17(q)</td><td></td></tr><tr><td>1806</td><td>180</td><td>1806</td><td>180</td><td>Submission of Information Disclosure Stmt</td><td>180.00</td></tr><tr><td>8021</td><td>40</td><td>8021</td><td>40</td><td>Recording each patent assignment per property (times number of properties)</td><td></td></tr><tr><td>1809</td><td>750</td><td>2809</td><td>375</td><td>Filing a submission after final rejection (37 CFR 1.129(a))</td><td></td></tr><tr><td>1810</td><td>750</td><td>2810</td><td>375</td><td>For each additional invention to be examined (37CFR 1.129(b))</td><td></td></tr><tr><td>1801</td><td>750</td><td>2801</td><td>375</td><td>Request for Continued Examination (RCE)</td><td></td></tr><tr><td>1802</td><td>900</td><td>1802</td><td>900</td><td>Request for expedited examination of a design application</td><td></td></tr><tr><td colspan="6">Other fee (specify) _____</td></tr><tr><td colspan="6" style="text-align: right;"><b>SubTOTAL (3) (\$ ) 180.00</b></td></tr></tbody></table>		Large Entity		Small Entity		Fee Description	Fee Paid	Fee Code	Fee (\$)	Fee Code	Fee (\$)	1051	130	2051	65	Surcharge - late filing fee or oath		1052	50	2052	25	Surcharge - late provisional filing fee or cover sheet.		1053	130	1053	130	Non-English specification		1812	2,520	1812	2,520	For filing a request for ex parte reexamination		1804	920*	1804	920*	Requesting publication of SIR prior to Examiner action		1805	1,840*	1805	1,840*	Requesting publication of SIR after Examiner action		1251	110	2251	55	Extension for reply within first month		1252	410	2252	205	Extension for reply within second month		1253	930	2253	465	Extension for reply within third month		1254	1,450	2254	725	Extension for reply within fourth month		1255	1,970	2255	985	Extension for reply within fifth month		1401	320	2401	160	Notice of Appeal		1402	320	2402	160	Filing a brief in support of an appeal		1403	280	2403	140	Request for oral hearing		1451	1,510	1451	1,510	Petition to institute a public use proceeding		1452	110	2452	55	Petition to revive - unavoidable		1453	1,300	2453	650	Petition to revive - unintentional		1501	1,300	2501	650	Utility issue fee (or reissue)		1502	470	2502	235	Design issue fee		1503	630	2503	315	Plant issue fee		1460	130	1460	130	Petitions to the Commissioner		1807	50	1807	50	Processing fee under 37 CFR 1.17(q)		1806	180	1806	180	Submission of Information Disclosure Stmt	180.00	8021	40	8021	40	Recording each patent assignment per property (times number of properties)		1809	750	2809	375	Filing a submission after final rejection (37 CFR 1.129(a))		1810	750	2810	375	For each additional invention to be examined (37CFR 1.129(b))		1801	750	2801	375	Request for Continued Examination (RCE)		1802	900	1802	900	Request for expedited examination of a design application		Other fee (specify) _____						<b>SubTOTAL (3) (\$ ) 180.00</b>							
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*Julie M. Hassell*  
Julie M. Hassell

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In the application of:

Philip J. BARR, et al

Serial No.: 10/025,514

Filing Date: December 18, 2001

For: MULTIFUNCTIONAL PROTEASE  
INHIBITORS AND THEIR USE IN  
TREATMENT OF DISEASE

Examiner: M. Walicka

Group Art Unit: 1652

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SUPPLEMENTAL INFORMATION DISCLOSURE  
STATEMENT UNDER 37 C.F.R. § 1.97 AND § 1.98

Mail Stop AF  
Commissioner for Patents  
P. O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

Pursuant to 37 C.F.R. § 1.97 and § 1.98, Applicants submit for consideration in the above-identified application the documents listed on the attached Form PTO-1449. A copy of the document is also submitted herewith. The Examiner is requested to make this document of record.

10/025514 00000069 031952 10005514

100.00 00

The document on the attached Form PTO-1449 was cited in an International Preliminary Examination Report mailed on June 27, 2003 (copy attached) directed to a counterpart international application and was not previously submitted.

This Supplemental Information Disclosure Statement is submitted:

- ☐ With the application; accordingly, no fee or separate requirements are required.
- ☐ Within three months of the application filing date or before mailing of a first Office Action on the merits; accordingly, no fee or separate requirements are required.
- ☐ After receipt of a first Office Action on the merits but before mailing of a final Office Action or Notice of Allowance.
  - ☐ A fee is required. A check in the amount of is enclosed.
  - ☐ A fee is required. Accordingly, a Fee Transmittal form (PTO/SB/17) is attached to this submission in duplicate.
  - ☐ A Certification under 37 C.F.R. § 1.97(e) is provided below; accordingly; no fee is believed to be due.
- ☒ After mailing of a final Office Action or Notice of Allowance, but before payment of the issue fee.
  - ☐ A Certification under 37 C.F.R. § 1.97(e) is provided below and a check in the amount of is enclosed.
  - ☒ A Certification under 37 C.F.R. § 1.97(e) is provided below and a Fee Transmittal form (PTO/SB/17) is attached to this submission in duplicate.

I hereby certify that each item of information was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement.

Applicants would appreciate the Examiner initialing and returning the Form PTO-1449, indicating that the information has been considered and made of record herein.

The information contained in this Information Disclosure Statement under 37 C.F.R. § 1.97 is not to be construed as a representation that: (i) a complete search has been made; (ii) additional information material to the examination of this application does not exist; (iii) the information, protocols, results and the like reported by third parties are accurate or enabling; or (iv) the above information constitutes prior art to the subject invention.

In the unlikely event that the transmittal letter is separated from this document and the Patent Office determines that an extension and/or other relief is required, Applicants petition for any required relief including extensions of time and authorize the Assistant Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing **368292000200**. However, the Assistant Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Dated: August 7, 2003

Respectfully submitted,

By: 

Eric Witt  
Registration No. 44,408

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Form PTO-1449

INFORMATION DISCLOSURE CITATION  
IN AN APPLICATION*(Use several sheets if necessary)*

Docket Number 368292000200

Application Number 10/025,514

Applicant

Philip J. BARR, et al

Filing Date December 18, 2001

Group Art Unit 1652

Mailing Date August 7, 2003

## U.S. PATENT DOCUMENTS

Examiner Initials	Ref. No.	Date	Document No.	Name	Class	Subclass	Filing Date If Appropriate
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## FOREIGN PATENT DOCUMENTS

Examiner Initials	Ref. No.	Date	Document No.	Country	Class	Subclass	Translation YES NO
	1.	11/19/1998	WO 98/51788	WIPO			

## OTHER DOCUMENTS

*(including author, title, Date, Pertinent Pages, Etc.)*

Examiner Initials	Ref. No.	Title
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**RECEIVED**

AUG 13 2003

TECH CENTER 1600/2900

EXAMINER:

DATE CONSIDERED:

EXAMINER: Initial if citation considered, whether or not the citation conforms with MPEP 609. Draw a line through the citation if not in conformance and not considered. Include a copy of this form with next communication to applicant.

# PATENT COOPERATION TREATY

# PCT

## INTERNATIONAL SEARCH REPORT

COPY

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference <b>368292000240</b>	<b>FOR FURTHER ACTION</b>		see Notification of Transmittal of International Search Report (Form PCT/ISA/220) as well as, where applicable, item 5 below.
International application No. <b>PCT/US 01/ 49256</b>	International filing date (day/month/year) <b>18/12/2001</b>	(Earliest) Priority Date (day/month/year) <b>18/12/2000</b>	
Applicant  <b>ARRIVA PHARMACEUTICALS, INC.</b>			

This International Search Report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This International Search Report consists of a total of 7 sheets.

☒ It is also accompanied by a copy of each prior art document cited in this report.

**1. Basis of the report**

a. With regard to the **language**, the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ the international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).

b. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international search was carried out on the basis of the sequence listing :

☐ contained in the international application in written form.

☐ filed together with the international application in computer readable form.

☒ furnished subsequently to this Authority in written form.

☒ furnished subsequently to this Authority in computer readable form.

☒ the statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

☒ the statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

2. ☒ **Certain claims were found unsearchable** (See Box I).

3. ☐ **Unity of invention is lacking** (see Box II).

4. With regard to the **title**,

☒ the text is approved as submitted by the applicant.

☐ the text has been established by this Authority to read as follows:

5. With regard to the **abstract**,

☒ the text is approved as submitted by the applicant.

☐ the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box III. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. The figure of the **drawings** to be published with the abstract is Figure No.

☐ as suggested by the applicant.

☐ because the applicant failed to suggest a figure.

☐ because this figure better characterizes the invention.

☐ None of the figures.

# INTERNATIONAL SEARCH REPORT

International application No.  
PCT/US 01/49256

## Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.:  
because they relate to subject matter not required to be searched by this Authority, namely:  
  
Although claims 26-35 are directed to a method of treatment of the human/animal body, the search has been carried out and based on the alleged effects of the compound/composition.
2. ☐ Claims Nos.:  
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. ☐ Claims Nos.:  
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

## Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. ☒ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☒ No protest accompanied the payment of additional search fees.



FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. Claims: 2,4,16,17 (all completely) and claims 1,5-14, 26-35 (all partially)

A fusion protein comprising alpha 1-antitrypsin (or a functionally active portion thereof) and secretory leukocyte protease inhibitor (or a functionally active portion thereof). A polynucleotide, an expression vector, a host cell and a pharmaceutical composition, all relating to said fusion protein.

2. Claims: 3,15,18-25 (all completely) and claims 1,5-14, 26-35 (all partially)

A fusion protein comprising alpha 1-antitrypsin (or a functionally active portion thereof) and tissue inhibitor of metalloproteases (or a functionally active portion thereof). A polynucleotide, an expression vector, a host cell and a pharmaceutical composition, all relating to said fusion protein.

## INTERNATIONAL SEARCH REPORT

Int'l Application No

PC1/US 01/49256

## A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 C12N15/62 C12N15/15 C07K14/81 A61K38/55 A61K38/57

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 C07K

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

CHEM ABS Data, SCISEARCH, LIFESCIENCES, SEQUENCE SEARCH, MEDLINE, BIOSIS, EMBASE, WPI Data, EPO-Internal, PAJ

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP 0 283 932 A (HOECHST AG) 28 September 1988 (1988-09-28)	1
Y	page 3, line 43 - line 46 ---	2-35
Y	BINGLE ET AL: "Secretory leukoprotease inhibitor: partnering alpha1-proteinase inhibitor to combat pulmonary inflammation" THORAX, LONDON, GB, vol. 51, no. 12, 1996, pages 1273-1274, XP002089585 the whole document --- -/--	2,4-14, 16,17, 26-35



Further documents are listed in the continuation of box C.



Patent family members are listed in annex.

## \* Special categories of cited documents :

- "A" document defining the general state of the art which is not considered to be of particular relevance
- "E" earlier document but published on or after the international filing date
- "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- "O" document referring to an oral disclosure, use, exhibition or other means
- "P" document published prior to the international filing date but later than the priority date claimed

- "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- "&" document member of the same patent family

Date of the actual completion of the international search

17 June 2003

Date of mailing of the international search report

27 JUN 2003

Name and mailing address of the ISA

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Authorized officer

Madruga, J

## C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	LEE GEOFFREY F ET AL: "Potent bifunctional anticoagulants: Kunitz domain-tissue factor fusion proteins." BIOCHEMISTRY, vol. 36, no. 19, 1997, pages 5607-5611, XP002231849 ISSN: 0006-2960	1
A	the whole document	2-35
A	SCHASTEEN C S ET AL: "SYNTHETIC PEPTIDE INHIBITORS OF COMPLEMENT SERINE PROTEASES-III. SIGNIFICANT INCREASE IN INHIBITOR POTENCY PROVIDES FURTHER SUPPORT FOR THE FUNCTIONAL EQUIVALENCE HYPOTHESIS" MOLECULAR IMMUNOLOGY, ELMSFORD, NY, US, vol. 28, no. 1/2, 1991, pages 17-26, XP001105438 ISSN: 0161-5890 the whole document	1-35
A	URWIN ET AL: "enhanced transgenic plant resistance to nematodes by dual proteinase inhibitor constructs" PLANTA, SPRINGER VERLAG, DE, vol. 204, April 1998 (1998-04), pages 472-479, XP002097968 ISSN: 0032-0935 the whole document	1-35
A	US 5 633 227 A (DELARIA KATHERINE A ET AL) 27 May 1997 (1997-05-27)  the whole document	1,2, 4-14,16, 17,26-35
A	POTEMPA J ET AL: "THE SERPIN SUPERFAMILY OF PROTEINASE INHIBITORS: STRUCTURE, FUNCTION, AND REGULATION" JOURNAL OF BIOLOGICAL CHEMISTRY, AMERICAN SOCIETY OF BIOLOGICAL CHEMISTS, BALTIMORE, MD, US, vol. 269, no. 23, 10 June 1994 (1994-06-10), pages 15957-15960, XP001120289 ISSN: 0021-9258 the whole document	1,2, 4-14,16, 17,26-35

-/--

## C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	<p>BARNES P J: "NOVEL APPROACHES AND TARGETS FOR TREATMENT OF CHRONIC OBSTRUCTIVE PULMONARY DISEASE"</p> <p>AMERICAN JOURNAL OF RESPIRATORY AND CRITICAL CARE MEDICINE, AMERICAN LUNG ASSOCIATION, NEW YORK, NY, US, vol. 160, no. 5, PART 2, November 1999 (1999-11), pages S72-S79, XP001098482</p> <p>ISSN: 1073-449X</p> <p>the whole document</p> <p>----</p>	1,2, 4-14,16, 17,26-35
Y	<p>WO 98 51788 A (VERHEIJEN JOHAN HENDRIKUS ;TNO (NL); QUAX PAULUS HUBERTUS ANDREAS)</p> <p>19 November 1998 (1998-11-19)</p> <p>page 3, line 12 - line 23</p> <p>page 6, line 16 - line 29</p> <p>----</p>	3,15, 18-25
A	<p>DOCHERTY A J P ET AL: "SEQUENCE OF HUMAN TISSUE INHIBITOR OF METALLOPROTEINASES AND ITS IDENTITY TO ERYTHROID-POTENTIATING ACTIVITY"</p> <p>NATURE, MACMILLAN JOURNALS LTD. LONDON, GB, vol. 318, 7 November 1985 (1985-11-07), pages 66-69, XP000650078</p> <p>ISSN: 0028-0836</p> <p>cited in the application</p> <p>the whole document</p> <p>----</p>	1,3, 5-15, 18-35
A	<p>MURPHY G ET AL: "THE N-TERMINAL DOMAIN OF TISSUE INHIBITOR OF METALLOPROTEINASES RETAINS METALLOPROTEINASE INHIBITORY ACTIVITY"</p> <p>BIOCHEMISTRY, AMERICAN CHEMICAL SOCIETY. EASTON, PA, US, vol. 30, no. 33, 20 August 1991 (1991-08-20), pages 8097-8102, XP000218096</p> <p>ISSN: 0006-2960</p> <p>cited in the application</p> <p>the whole document</p> <p>-----</p>	1,3, 5-15, 18-35

# INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/US 01/49256

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
EP 0283932	A	28-09-1988	DE 3709255 A1	29-09-1988
			AU 611676 B2	20-06-1991
			AU 1328888 A	22-09-1988
			DK 151788 A	21-09-1988
			EP 0283932 A2	28-09-1988
			FI 881268 A	21-09-1988
			HU 46740 A2	28-11-1988
			JP 63267294 A	04-11-1988
			PT 87009 A ,B	01-04-1988
			ZA 8801948 A	28-12-1988
US 5633227	A	27-05-1997	AT 234117 T	15-03-2003
			CA 2199746 A1	21-03-1996
			DE 69529912 D1	17-04-2003
			EP 0787016 A1	06-08-1997
			JP 10505833 T	09-06-1998
			WO 9608275 A1	21-03-1996
WO 9851788	A	19-11-1998	AU 7553698 A	08-12-1998
			EP 0981606 A2	01-03-2000
			JP 2001525669 T	11-12-2001
			WO 9851788 A2	19-11-1998
			NO 995564 A	11-01-2000
			NZ 500656 A	30-11-2001